

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

**FILED**

**MAR 30 2009.**

UNITED STATES OF AMERICA *ex rel.*  
MELISSA THEIS, and MELISSA  
THEIS, individually,  
Plaintiffs,

v.

NORTHWESTERN UNIVERSITY,  
THE ROBERT H. LURIE COMPREHENSIVE  
CANCER CENTER OF NORTHWESTERN  
UNIVERSITY, DR. STEVEN T. ROSEN, AND  
DR. CHARLES L. BENNETT.  
Defendants.

THOMAS G BRUTON  
CLERK U S DISTRICT COURT

NO. \_\_\_\_\_

CHIEF JUDGE HOLDERMAN  
**FILED UNDER SEAL**

09CV 1943  
JUDGE HOLDERMAN  
MAG. SCHENKIER

**FALSE CLAIMS ACT COMPLAINT  
AND DEMAND FOR JURY TRIAL**

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The United States of America *ex rel.* Melissa Theis, and Melissa Theis, individually (collectively "plaintiffs"), state as follows for their Complaint against Northwestern University, Dr. Charles L. Bennett, Dr. Steven T. Rosen and The Robert H. Lurie Comprehensive Cancer Center of Northwestern University, collectively ("defendants"):

## **I. INTRODUCTION**

1. This is an action by the United States of America through the Relator Melissa Theis ("Relator Theis" or "Theis"), to recover treble damages and civil penalties arising from false statements and claims made, used or caused to be made by the defendants Northwestern University ("Northwestern"), Dr. Charles L. Bennett ("Dr. Bennett"), Dr. Steven T. Rosen ("Dr. Rosen"), and The Robert H. Lurie Comprehensive Cancer Center of Northwestern University ("RHLCCC"), collectively ("defendants"), to the United States, in violation of the federal False Claims Act, 31 U.S.C. §§3729-33.

2. Defendant Northwestern is a private University which is comprised of a number of undergraduate and graduate units. In addition to educating students, Northwestern also conducts scientific research which is largely funded by federal grants.

3. To apply for and receive federal National Institute of Health ("NIH") grants, Northwestern is the grantee institution which actually receives money from the federal government. A specific researcher at Northwestern must serve as the grant's Principle Investigator ("PI"). The PI is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and the grant's issuing agency for the proper conduct of the project or activity, including how the grant money is spent and accounted for.

4. Each year researchers at Northwestern apply for and receive millions of dollars in grants from the NIH, the National Cancer Institute (“NCI”) and the U.S. Department of Health and Human Services (“HHS”).

5. HHS is the grant’s “issuing agency”, the NIH acts as the grant’s “operating division” and the NCI serves as the grant’s “program office.” Both the NIH and the NCI fall under the umbrella of HHS. All three of these agencies play a significant role in the grant application, review, award, and management process.

6. Since at least January 1, 2003, researchers at Northwestern’s Feinberg School of Medicine (“Feinberg School”) have applied for and received over \$130 million in federal grants from the NIH through the NCI. A significant portion of these grants went to physicians in the Feinberg School’s Division of Hematology and Oncology (“Hematology and Oncology”) and to help fund research and treatment at the RHLCCC.

7. Defendants Dr. Bennett and Dr. Rosen were researchers at Northwestern’s Feinberg School, who were listed as PIs on numerous NIH / NCI grants during the relevant time. Dr. Bennett and Dr. Rosen also engaged in patient care at Northwestern Memorial Hospital and conducted research through the RHLCCC.

8. In order to receive its extensive grant funding, Northwestern’s researchers must submit applications to the federal government. Typically a grant application will contain detailed information about the grantee institution (Northwestern), the grant’s PI(s) and other contributing personnel, an overview of the research or project for which funding is sought, the resources and support provided by the grantee institution, and a comprehensive budget.

9. As part of its application, the grantee and PI must also make specific certifications and assurances to HHS, the NIH and the NCI. These certifications and assurances: (1) require the grantee to provide true, complete and accurate information in its application; (2) obligate the grantee to abide by the Grant Application Guide and the *NIH Grants Policy Statement*, and; (3) require the grantee to acknowledge that any false or fraudulent statements or claims may lead to criminal, civil or administrative penalties.

10. The Grant's Application Guide and the *NIH Grants Policy Statement* incorporate by reference, and require compliance with, numerous federal statutes, Code of Federal Regulations ("CFR") provisions and Office of Budget Management ("OBM") Circulars.

11. These sources establish the rules and requirements for institutions and PIs applying for grants in a number of key areas including: grant accounting; financial management and cost principles; grant administration procedures; grant audit requirements; grant reporting obligations, and; grant closeout procedures.

12. The OBM, HSS, the NIH and the NCI specifically promulgate these regulations, policy statements and circulars to prevent and uncover fraud. While these sources address a wide variety of topics, the fundamental, overarching theme is that the grantee and PI are ultimately responsible for federally funded grants.

13. Defendants have, and continue to, violate the *NIH Grants Policy Statement*, OBM Circulars and federal regulations that apply to: (1) basic cost principles; (2) the need to obtain prior approval for significant budget modifications; and (3) time/effort reporting procedures.

**A. Basic Cost Principles**

14. When seeking funds under a federal grant, the grantee and PI are subject to a series of cost principles. These cost principles are designed to ensure that any expenses paid from federal grants are reasonable, will directly benefit the work done under the grant, will conform to the requirements of the applicable OBM Circulars, and will follow the terms of the Notice of Grant Award ("NGA"). A cost which meets all of these requirements is deemed to be "allowable" and can be properly charged to a federal grant.

15. OBM Circular A-21 also lists a number of specific categories of expenses which are per se unallowable. For example "entertainment costs," or "goods and services for personal use" are unallowable costs under all circumstances.

16. Costs which are unallowable need to be clearly identified and cannot be included in any billing, claim, application or grant proposal. If an unallowable cost is paid under a federal grant, the grantee must refund the money to the grant's issuing agency.

17. By way of example, defendant Dr. Bennett submitted and received reimbursement from NIH grants for travel expenses incurred on trips with his family, and for which he incurred charges which were highly excessive. These costs are unallowable pursuant to the standards in OBM Circular A-21.

18. Defendants submitted false claims when they sought and received payment for unallowable costs. Defendants' conduct in concealing their obligation to repay these unallowable costs for which they received federal money also gives rise to reverse false claims. Finally, by failing

to follow the OBM Circulars, Northwestern's application and the certifications of compliance amount to false claims.

**B. Budget Modifications and Prior Approval**

19. As part of its application a grantee is required to submit a detailed budget for approval. Using the submitted budget the NIH / NCI issue the NGA which sets forth the total award and breaks down the available funds for each distinct budget category.

20. Given the realities of conducting scientific research, there may be disparities between the estimated costs for materials, goods and services as included in the application budget and the actual costs. Accordingly, the NIH allows grantees to made modifications or re-budget within certain limitations.

21. Significant re-budgeting and deviation from the budget in the NGA is not permitted unless a grantee first obtains the NIH's written approval. Prior approval requirements exist to safeguard federal grant money and prevent the expenditure of funds on items which the NIH has not approved. This requirement is found in the *NIH Grants Policy Statement*.

22. The defendants engaged in significant re-budgeting without obtaining prior approval from the NIH. By way of example, Dr. Bennett submitted or caused to be submitted invoices for vendors and consultants which were either not initially included in the budget or significantly deviated from the budgeted amounts in the NGA. Dr. Bennett failed to obtain prior approval for these expenses.

23. With respect to numerous NIH / NCI grants, defendants submitted false claims when they sought and received payments from grant funds for costs that were not included in the NGA or

constituted a significant re-budgeting and required written prior approval from the NIH. By failing to comply with the prior approval requirements found in the *NIH Grants Policy Statement* and OBM Circular A-110, Northwestern's grant applications and the certifications of compliance amount to false claims.

**C. Effort Reporting Procedures**

24. Researchers who work on federal grants are paid their salary based on a process referred to as "effort reporting". Through effort reporting, a researcher will record and quantify the amount of time they have spent working on a particular federal grant. As part of its application, the grantee includes an estimate outlining the amount of time a PI and researchers plan to devote to a grant.

25. The general grant cost principles apply not only to expenses but to effort reporting as well. Among the cost principles, allocation is the most relevant in the context of effort reporting. Because many university researchers often work on several government grants during an academic year, accurately allocating and reporting effort on each grant is very important.

26. Researchers must be careful not to co-mingle their effort among different grants if they are unable to approximate with reasonable certainty the actual time they spent working on a single grant.

27. Much like ordinary budget items included in the grant application, the proposed or estimated effort a PI or researcher's plans to expend on a grant tends to vary from what actually occurs. Given this reality, OMB Circular A-21 establishes a number of effort reporting procedures which require that effort reports be verified to ensure that a researcher actually performed the work



for which they are receiving payment. Additionally, grantees are required to reconcile estimated and actual effort reports so that any excess grant funds which were budgeted or paid to the grantee will be returned to the grant's issuing agency.

28. The defendants failed to adhere to the effort reporting requirements set forth in the *NIH Grants Policy Statement* and OBM Circular A-21. By way of example, Dr. Bennett failed to accurately allocate his effort reporting while working on several NIH grants at once.

29. With respect to numerous NIH / NCI grants, defendants presented or caused to be presented, false claims when they submitted effort reports which were not properly allocated and violated grant cost principles, allowing defendants to seek and receive payments from grant funds. Defendants' conduct in failing to properly reconcile estimated and actual researcher effort allowed defendants' to avoid and conceal their obligation to refund grant money to the issuing agency and amounts to reverse false claims. Finally, by failing to comply with the effort reporting requirements found in the *NIH Grants Policy Statement* and OBM Circular A-21, Northwestern's grant applications and the certifications of compliance amount to false claims.

## **II. JURISDICTION AND VENUE**

30. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§3729-3730. This court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) pursuant to 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and, (iii) pursuant to 28 U.S.C. §1345, because the United States is a plaintiff.

31. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit, or investigation, or in a government Accounting Office or Auditor General's report, hearing, audit, or investigation, or from the news media.

32. To the extent that there has been a public disclosure unknown to Theis, Theis is an original source under 31 U.S.C. §3730(e)(4). She has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government before filing an action under this section, which is based on the information.

33. Plaintiff Theis is concurrently providing to the Attorney General of the United States, and to the United States Attorney for the Northern District of Illinois, a statement summarizing known material evidence and information related to the Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). This disclosure statement is supported by material evidence.

34. This court has personal jurisdiction over defendants under 31 U.S.C. §3732(a) because defendants can be found, reside, or transact business in this District, or an act proscribed by 31 U.S.C. §3729 occurred in this District. The defendant has made, used, or caused to be made or used, false or fraudulent records in this District to get false or fraudulent claims paid or approved by the government. Venue is proper in this District under 31 U.S.C. §3732(a) and 28 U.S.C. §1391.

### **III. PARTIES**

35. Plaintiff and Relator Melissa Theis is a citizen and resident of the State of Illinois. She brings this action on her own behalf and on behalf of the government pursuant to 31 U.S.C. §3730(b)(1).

36. Defendant Northwestern University ("Northwestern"), is a private not-for-profit

University incorporated in Illinois, with campuses located in Chicago and Evanston, Illinois. In addition to serving as an academic institution, many of Northwestern's departments conduct scientific research with the assistance of federal grants. One of these departments is Northwestern's Feinberg School of Medicine ("Feinberg School").

37. Defendants Dr. Charles L. Bennett ("Dr. Bennett") and Dr. Steven T. Rosen ("Dr. Rosen") were researchers at Northwestern's Feinberg School who were listed as Primary Investigators ("PIs") on numerous NIH and NCI grants during the relevant time.

38. Between at least 2003 and the present Dr. Bennett, Dr. Rosen were listed as PIs on federal grants exceeding \$8 million and \$32 million respectively.

39. Defendant The Robert H. Lurie Comprehensive Cancer Center of Northwestern University ("RHLCCC"), is an institution affiliated with The Feinberg. Dr. Rosen serves as the RHLCCC's Director. Initially the result of a private endowment, since 1998 the RHLCCC is now primarily funded by federal NCI grant money. Since 2003, the RHLCCC has received nearly \$42 million from the NCI. Dr. Rosen and Dr. Bennett were involved in research and patient care through the RHLCCC.

#### **IV. DEFENDANTS KNOWINGLY PRESENTED FALSE CLAIMS**

##### **A. Grantee's Certifications, Assurances and Compliance Obligations**

40. The Government holds Northwestern accountable for how funding from federal research grants is acquired and spent.

41. Beginning with their initial application for federal funding, grantees are required to make specific certifications and assurances to the issuing agency (HHS), operating division (NIH)

and program office (NCI). Northwestern, like all grantees, must adhere to the strict rules and regulations about how grant money will be spent, and the conduct and activities of the grantee and PI.

42. Before approximately February of 2007, grant applicants, including Northwestern, who sought funding from the NIH were required to complete a PHS 398 application. In completing the PHS 398 application grantees were required to certify that:

The statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

\*\*\*\*\*

In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after this page. [Emphasis supplied]

(PHS 398 Application, Page 1, 9)

43. In August 2005, the NIH announced a plan to transition from the PHS 398 application to the SF 424(R&R) application which would be submitted electronically. The NIH set a tentative deadline for all institutions applying for R01 grants to use the SF 424(R&R) application by February, 2007.

44. Much like the PHS 398, the SF424(R&R) application requires the grantee to certify that:

By signing the application, I certify (1) to the statements contained in the list of certifications\* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances\* and agree to

comply with any resulting terms if I accept an award. I am aware that an false, fictitious or fraudulent statements or claims may subject me to criminal, civil or administrative penalties. [Emphasis supplied]

(SF 424(R&R) Application, Page 2)

45. Under most circumstances, applicants using the SF 424(R&R) must also complete portions of the PHS 398 application including the cover sheet and certifications.

46. The SF 424(R&R) and PHS 398 also include Application Guides.

47. These Application Guides require that the applicant organization secure and retain a written assurance from the Principle Investigator. This assurance must be made available to the sponsoring agency upon request and needs to contain at least the following certifications:

(1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and (3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs. [Emphasis supplied]

(SF 242(R&R) Application Guide: Part III, Section 2.14)

48. The PHS 398 Application Guide requires the grantee institution to obtain an identical certification from the Principle Investigator. (See PHS 398 Application Guide: Part III, Section 2.14).

49. The SF 424(R&R) and the PHS 398 also incorporate by reference the *NIH Grants Policy Statement*. Specifically, the Application Guides make it clear that by virtue of signing the face page of the grant application, the grantee certifies their compliance with an obligation to abide by the *NIH Grants Policy Statement*.

50. The *NIH Grants Policy Statement* is the authoritative publication that provides all critical information that the grantee needs to know. As the NIH explains in The Grants Policy Statement Introduction: “The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH grantees, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards.”

51. The three most important areas of compliance with respect to federal grants are: (1) Administrative Requirements; (2) Cost Principles, and; (3) Audit Requirements. The *NIH Grants Policy Statement* incorporates by reference specific Code of Federal Regulations provisions and OBM Circulars that apply to each of these compliance areas. Based on the certifications and assurances found in its grant application, the grantee and the PI are required to strictly abide by these Regulations and Circulars.

52. The specific CFR provisions that apply to a given grant are determined by the type of grantee institution. Based on Northwestern’s status as “college or university”, Circular A-21 (codified at 2 CFR Part 215) and Circular A-110 (codified at 2 CFR Part 230) apply.

53. Through its grant application, the grantee is also bound by any terms or conditions which are part of the Notice of Grant Award (“NGA”). The NGA addresses a number of issues including the total amount of the award and the amount budgeted for specific costs such as salaries, consultant services, equipment and travel.

**B. Defendants Submitted False Claims by Seeking Payment of and Failing to Refund Unallowable Costs**

54. When Northwestern submitted its SF 424(R&R) and PHS 398 applications, it certified that it would comply with all terms and conditions set forth in the *NIH Grants Policy*

*Statement*, the relevant CFR and OBM provisions and the NGA to only submit claims for payment which are allowable. (See SF 424 (R&R) and PHS 398 Application Guide(s): Part III, Section 2; *NIH Grants Policy Statement*: Part II, Page 74, 79-80).

55. The purpose of OBM Circulars A-21 and A-110 is to ensure that the government only pays costs under a federal grant which are allowable.

56. In order for any cost of work performed under a grant to be allowable, the cost must be: (1) reasonable; (2) allocable to the grant based on the accounting principles in OMB Circular A-21; (3) given consistent treatment through the use of generally accepted accounting standards, and; (4) conform to any limitations or exclusions set forth in OMB Circular A-21 or the grant's notice of award with respect to both the types or amounts of cost items. (OMB Circular A-21, §C.2).

57. The reasonableness of a given cost should reflect the action that a prudent person would have taken under the same circumstances at the time the decision was made. Factors examined in determining reasonableness include: the generally recognized necessity of the cost; restraints and requirements imposed by factors such as arms-length transactions and adherence to federal and state laws and regulations, and the notice of award; the due prudence exercised by an individual in light of their duty to the institution, its employees the Federal Government and the public at large, and; the extent to which incurring costs were consistent with institutional policies and practices. (OMB Circular A-21, §C.3).

58. A PI can use the grant for the cost of goods or services that are either incurred solely to advance the work under the grant or benefit both the grant and other work of the institution in proportions that can be approximated by the use of reasonable methods. (OMB Circular A-21,

of the amounts to which the recipient is financially determined to be entitled under the terms and conditions of the award constitute a debt to the Federal Government.  
[Emphasis supplied]

(OBM Circular A-110, §D.71(d) and §D.73(a)).

63. Since at least 2003, Northwestern has applied for and received payment for unallowable costs. Northwestern has failed to properly account for these unallowable costs and refund the government as is required by OBM circular A-21, A-110 and the *NIH Grants Policy Statement*.

64. By way of example, Dr. Bennett, one of the PIs in Hematology and Oncology, obtained reimbursement under federal government grants for: trips with his family, travel which occurred on a near weekly basis, and in some cases incurred expenses which were highly excessive.

65. Pursuant to OBM Circular A-21 “entertainment costs,” “goods and services for personal use” and “housing and personal living expenses” are expressly deemed to be unallowable. Any “travel costs” must only be for reasonable charges in accordance with the grantee institution’s travel policy and practices, otherwise they will also be deemed as unallowable. (OMB Circular A-21, §§J.15,19,20,48).

66. Based on the cost principles found in OBM Circular A-21, the travel reimbursement requests submitted by Dr. Bennett are unallowable.

67. Beyond requests for travel reimbursement, defendants engaged in a broad-based scheme to submit and receive payment for costs which they knew were unallowable. This occurred most frequently with respect to the selection of vendors and consultants who worked on federal grants.



68. Defendants chose vendors and consultants without first obtaining additional bids for work to be performed, failed to use “in-house” resources which would have been sufficient to meet the project needs, and awarded contracts based on personal relationships with the vendors.

69. The costs incurred by the defendants are not objectively reasonable, do not constitute the actions of a “prudent person” and are strongly in conflict with OBM Circular A-21’s admonition that an assessment of reasonableness should take into account “restraints and requirements imposed by factors such as arms-length transactions, adherence to federal and state laws and regulations.” (OBM Circular A-21 §C.3).

70. Furthermore, defendant Northwestern has failed to implement or oversee the implementation of appropriate procedures and safeguards to prevent the submission of unallowable costs and ensure the repayment of federal grant money received based on unallowable costs.

71. By knowingly presenting or causing to present a false or fraudulent claim for payment or approval from a government grant for costs that are unallowable in violation of OBM circular A-21 and the *NIH Grants Policy Statement*, defendant submitted, or caused to be submitted, false claims.

72. By certifying that they would properly account for and refund grant money that was paid by the government for unallowable costs in accordance with OBM circular A-21 and the *NIH Grants Policy Statement*, and fraudulently failing to do so, defendants made, used or caused to be used, a statement or record to conceal, avoid or decrease an obligation to the United States; the statements and records were false and fraudulent; the defendants knew the statements and records were false and fraudulent; and the defendants made a false statement or record at a time that

defendants owed to the government an obligation sufficiently certain to give rise to an action of debt at common law. Northwestern's conduct of using a false statements or records to avoid paying a debt or obligation to the United States gives rise to a reverse false claim.

73. Further information which outlines the particulars of the specific false claims submitted to the government are within the exclusive possession and control of the defendants. Documents that reflect the fraud include: PHS 398 and SF 424(R&R) Grant Applications and accompanying materials; Notice of Grant Awards; travel reimbursement requests with supporting documentation; invoices for vendors / consultants or services submitted for work on federal grants, and; budget statements documenting allowable and unallowable costs.

**C. Defendants Filed False Claims When They Submitted Requests for Unbudgeted Costs Without First Obtaining Prior Approval From the NIH**

74. While grantees are allowed some latitude to re-budget within and between budget categories to meet unanticipated needs and make other types of post-award changes, the *NIH Grants Policy Statement* sets forth a series of requirements with respect to these changes. To ensure the proper use of federal grant money and the issuing agencies goals in awarding grants, certain re-budgeting and post-award changes require written prior approval from the NIH.

75. In many instances re-budgeting funds for direct costs does not require any type of prior approval, however, a "change in scope" of the grant will always require NIH prior approval. Included in the events that will trigger a change in scope is any "significant re-budgeting" where a single direct cost budget category deviates from the categorical commitment level by more than 25% of the total costs awarded. (OBM Circular A-110 §C.25)

76. Prior approval is also required when there is a deviation from the award terms and

conditions as stated in the NGA. Grant applicants (including Northwestern) are required to submit detailed budgets as part of their PHS 398 and SF 424(R&R) application, which specifically break down the categories and amounts for direct costs. The NIH uses these budgets to create the NGA which will frequently itemize or categorize the awarded costs.

77. The budget plan which serves as the financial expression of a project is approved during the award process. OMB Circular A-110 requires a grant recipient report deviations from budget and program plans initially submitted. (OMB Circular A-110, §C.25).

78. Since at least 2003, the defendants engaged in significant re-budgeting which resulted in a change in scope under the grant. Northwestern failed to obtain written prior approval from the NIH for these changes and did not notify the NIH of deviations in their budget and program plans. Additionally, the defendants used grant funds in a manner that deviated from the award terms and conditions as set forth in the NGA. Northwestern failed to obtain written prior approval for these deviations.

79. By way of example, Dr. Bennett, one of the PIs in Hematology and Oncology, frequently sought and obtained payment under federal grants for consultant services that were never budgeted or included in the budget portion of the SF 424(R&R) application. In one case, between January 1, 2008 and December 31, 2008, Dr. Bennett authorized nearly \$250,000 in federal grant money used to pay consultants who were never budgeted. These vendor and consultant payments were especially troubling because they were accelerated draw-downs which occurred near the end of the grants' budget periods.

80. The above mentioned vendors and consultants were paid using funds from NIH grant

numbers: R01CA102713-02REV, R01CA102713-02S3, R01CA102713-02S1, R01CA125077-01A1, and R01HL069717-04.

81. Pursuant to the *NIH Grants Policy Manual's* guidelines, Dr. Bennett's extensive use of consultants who were not included in the SF 424(R&R) application would be deemed as a change in scope because of the significant re-budgeting required. As Dr. Bennett failed to obtain written prior approval from the NIH for this re-budgeting his conduct violated the *NIH Grants Policy Manual*.

82. Additionally, Dr. Bennett's ad hoc re-budgeting and use of vendors and consultants not included in the initially submitted budget would materially depart from the NGA. As Dr. Bennett failed to obtain written prior approval for these deviations they would violate the terms of the NGA and the *NIH Grants Policy Statement*.

83. Defendant Northwestern's failure to implement, or oversee the implementation of, appropriate procedures and safeguards to prevent inappropriate re-budgeting and deviation from federal NGAs, created a broad-based scheme to skirt the reconciliation and prior approval requirements found in the *NIH Grants Policy Statement* and OBM Circular A-110.

84. Defendants' submission of improper requests for federal grant money based on their failure to obtain prior approval as required by the *NIH Grants Policy Statement* and OBM Circular A-110, amount to false claims.

85. Based on Northwestern's failure to comply with the *NIH Grants Policy Statement* and OBM Circular A-110, Northwestern's SF 424(R&R), PHS 398 grant applications and the certifications of compliance are also false claims.

86. Further information which outlines the particulars of the specific false claims submitted to the government are within the exclusive possession and control of the defendants. Documents that reflect the fraud include: PHS 398 and SF 424(R&R) Grant Applications and accompanying materials; Notice of Grant Awards; submitted requests for prior approval to re-budget, and; grant budget statements.

**D. Defendants Submitted False Claims by Failing to Accurately Report and Reconcile Time/Effort Statements for its Researchers**

87. Researcher and PI salaries frequently constitute one of the largest areas of direct cost for a federal grant.

88. Like any other direct cost, researcher salaries must be: (1) reasonable; (2) allocable; (3) given consistent treatment based on accepted accounting practices, and; (4) in conformance with limitations or exclusions set forth in OMB Circular A-21 or the NGA. (OMB Circular A-21, §C.2).

89. Researcher and PI salaries from federal grants are determined based on a concept referred to as effort reporting. Effort reporting is the process by which primary investigators or researchers quantify the estimated time they will spend and the time actually expended on a grant.

90. Effort reporting is usually done as a function of "person hours," although it may also be reported as a percentage of the researcher's total time spent working on grants and other responsibilities such as faculty or administrative functions through the university (grantee institution).

91. As part of the SF 424(R&R) and PHS 398 applications a grantee institution is required to submit a budget which reports the estimated effort that the PI or researcher plans to spend on a given grant. This estimate is then used by the NIH to determine the amount of approved funding for researcher and PI salaries in the NGA.

92. Typically effort reporting policies and procedures are created and implemented at the institutional level. Given the importance of effort reporting and the significant amount of federal funding at stake, OMB Circular A-21 requires that with respect to the method of effort reporting used by a grantee:

The [effort reporting] method must recognize the principle of after-the-fact confirmation or determination so that costs distributed represent actual costs... Direct cost activities and F&A cost activities may be confirmed by responsible persons with suitable means of verification that the work was performed. Confirmation by the employee is not a requirement for either direct or F&A cost activities if other responsible persons make appropriate confirmations. [Emphasis supplied]

OBM Circular A-21, §J.8(b)(2)

93. OBM Circular A-21 requires a process of reconciliation between estimated and actually expended effort so that salaries reflect no more than the percentage of time actually performed on a given grant.

94. The principle that salaries (costs) must be allocable is particularly important at larger institutions when a researcher or PI will frequently work on several different federal grants during a single academic year. Because the effort expended must be directly traceable to advancing the work under a specific grant (allocable) when working on multiple grants during the same timeframe, a researcher or PI's effort reporting should reflect an accurate approximation of the time spent on each grant. (OMB Circular A-21, §C.4).

95. Since at least 2003, defendants have failed to comply with the effort reporting and reconciliation requirements found in OBM Circular A-21 and have submitted effort reports that are not in accordance with the general cost principles established in OBM Circular A-21 for all NIH

grants.

96. Because Northwestern failed to implement and oversee a proper effort reporting and reconciliation system, defendants were able to submit and receive payment for effort reports that were not in compliance with OBM Circular A-21, leading to the presentation of false claims.

97. By way of example, Dr. Bennett worked on multiple grants at a single time. This practice was not uncommon, as researchers in Hematology and Oncology and defendant the RHLCCC receive significant funding from the NIH, PIs and researchers frequently will work on several NCI grants at the same time.

98. When working on multiple grants during a single academic year, Dr. Bennett failed to properly allocate his effort proportionally to each grant. In direct violation of the requirements found in OBM Circular A-21, Dr. Bennett would co-mingle his effort reporting and allocate time in a manner that was most advantageous to his own interest based on which grants had available funding for direct costs (like researcher salaries).

99. This type of practice also creates serious problems because of the grantee's obligation to perform a subsequent reconciliation of the estimated effort included in the PHS 398 or SF 424(R&R) budget statement with the actual effort expended by PIs and researchers.

100. The Grants Monitoring Office ("GMO") monitors grantee expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the grantee's associated budget, including the availability of unobligated balances. Although NIH allows its grantees certain flexibilities with respect to re-budgeting the NIH expects

the rate and types of expenditures to be consistent with the approved project and budget.

101. The GMO may review grantee cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the grantee's financial management system or internal controls.

102. The defendants also engaged in a troubling pattern of accelerated draw-downs near the end of grant budget periods. By way of example, Dr. Bennett would allocate any disbursed but unused funds for his salary when his grants were nearing the end of their budget period. This was done because the unused amounts would not have been permitted to carry over to the next budget period or needed to be returned to the government.

103. Defendants presented false claims when they submitted effort reports for payment that failed to comply with the cost principles established in OBM Circular A-21.

104. Defendants also submitted false claims when researchers, PIs or "responsible persons" submitted the "after the fact" certification to verify effort reports pursuant to the methods proscribed by OBM Circular A-21.

105. Defendants' conduct in failing to properly reconcile estimated effort with actual effort reported and deliberately drawing down on unused funds to at the end of budget periods, served to conceal or avoid an obligation to pay or refund money to the grant's issuing agency and gives rise to a reverse false claims.

106. Based on Northwestern's failure to comply with the *NIH Grants Policy Statement* and OBM Circular A-21 in regard to effort reporting and reconciliation procedures, Northwestern's SF



424(R&R) and PHS 398 grant applications and the certifications of compliance are also false claims.

107. Further information which outlines the particulars of the specific false claims submitted to the government are within the exclusive possession and control of the defendants. Documents that reflect the fraud include: PHS 398 and SF 424(R&R) Grant Applications and accompanying materials; Notice of Grant Awards; original and reconciled effort reports submitted by researchers and PIs working on federal grants; reports and documentation showing “after the fact” certification or verification of researcher effort reports, and; Northwestern’s institutional policies regarding effort reporting and procedures to verify effort reports.

**E. False Claims Were Submitted or Caused to be Submitted Based on Defendant Northwestern’s Failure to Implement and Oversee a Proper Financial Management System**

108. Northwestern’s failure to implement and oversee a proper financial management system created false or fraudulent claims to be submitted by Northwestern for all federal grants issued to Northwestern. While a proper financial management system is required to obtain and receive federal grants, Northwestern knowingly failed to provide fundamental controls and accounting.

109. According to OBM Circular A-110, which establishes the administrative requirements for colleges and universities receiving federal grants, a grantee must implement a financial management system which appropriately safeguards grant funds, has written policies and procedures for determining the allowability of costs and provides for proper documentation of the costs paid from grants.

110. OBM Circular A-110 specifically provides:

(3) Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes.

(6) Written procedures for determining the reasonableness, allocability and allowability of costs in accordance with the provisions of the applicable Federal cost principles and the terms and conditions of the award.

(7) Accounting records including cost accounting records that are supported by source documentation.

(OBM Circular A-110 §C.22).

111. A financial management system is implemented and managed at the institutional level. The review and payment of invoices, travel reimbursement request and effort reports is typically performed by the universities' accounting services branch of the Office for Sponsored Research. Based on the broad scale with which a financial management system is deployed, even small deficiencies are magnified and can have a serious effect.

112. Bruce Elliott and Susan Ross serve as the directors of Northwestern's Office of Sponsored Research.

113. Because Northwestern failed to implement and oversee a proper financial management system, in material non-compliance with the requirements of OBM Circular A-110 §C.22 (3) and (6), defendants' were able to submit and receive payment for unallowable costs which were not refunded or repaid to HHS. Defendants' ability to engage in significant re-budgeting, and accelerated draw-downs is also a direct result of Northwestern's deficient financial management system.

114. Because Northwestern failed to implement and oversee a proper financial management system, in material non-compliance with the requirements of OBM Circular A-110

§C.22 (3) and (7), Northwestern paid vendors and consultants based on invoices which failed to sufficiently document or outline the work they had performed on NIH grants.

115. In February of 2003, Northwestern University agreed to pay the United States \$5.5 million as part of a settlement for alleged False Claims Act violations which occurred with respect to the use of federal research funds from NIH grants.

116. Defendant Northwestern presented false claims or caused false claims to be presented based on its material non-compliance with the OBM Circular A-110 and failure to implement an appropriate financial management system.

117. Further information which outlines the particulars of the specific false claims submitted to the government are within the exclusive possession and control of the defendants. Documents that reflect the fraud include: Northwestern's institutional policies regarding the implementation, management and oversight of its financial management system, and; employee handbooks, manuals and training materials that deal with Northwestern's financial management system.

#### **V. RELATOR THEIS' DISCOVERY OF THE FRAUD**

118. Relator Theis began working at Northwestern's Feinberg School of Medicine in November of 2007 as a purchasing coordinator in Hematology and Oncology. Relator Theis was placed into this position through a temporary staffing agency. In February of 2008, Relator Theis was hired as a full time employee by the Northwestern Medical Faculty Foundation ("NMFF").

119. Despite that fact that she was hired by NMFF, Theis worked almost exclusively on matters involving and related to Northwestern.

120. Relator Theis was responsible for the review and processing of invoices and travel reimbursement requests submitted by researchers and PIs working on private and government grants in her capacity as a purchasing coordinator. Almost immediately, Relator Theis noticed irregularities or "red flags" with respect to the invoices and reimbursement requests being submitted on federal grants.

121. Relator Theis observed numerous problems and irregularities with respect to unreasonable travel reimbursement from federal government grants and invoices submitted by consultants and vendors working on federal government grants.

122. Theis specifically noted that: invoices were submitted for consultants and services that were never included in the initial grant budget; invoices were submitted for consultants and services that were significantly in excess of the amount budgeted for the grant, and; many of the consultants and vendors failed to provide detailed information about the actual services they rendered.

123. With respect to time and effort reporting on federal grants, Relator Theis noticed that the PIs would frequently draw down any excess grant funds for salary payments near the end of a budget period. Theis was also aware that PIs effort reports failed to control co-mingling and properly allocate a researcher's time to a particular grant while they were working on multiple grants during a given budget period.

124. The conduct Theis witnessed is particularly serious as grantees are obligated to submit effort reports to the government with their initial budget and perform a subsequent reconciliation between their estimate and the effort actually expended, such that any excess funding is returned to

the agency issuing the grant.

125. Based on her concerns about the propriety of what she had observed, in September of 2008, Theis spoke with her supervisor Angela YoungFountain ("YoungFountain"). Theis and one of her co-worker's Alice Camacho ("Camacho"), also contacted Northwestern's Accounting Services for Research and Sponsored Programs ("ASRSP").

126. Despite her efforts, Northwestern refused to seriously address the issues she had brought to YoungFountain and the ASRSP

127. Theis voluntarily left her position at Northwestern on October 31, 2008 due to the problems that she had observed and Northwestern's apparent failure to properly investigate and take corrective action regarding the expenditure and accounting of federal grant money.

**COUNT I**  
**False Claims Act**

128. Plaintiffs incorporate by reference and re-allege Paragraphs 1 through 127 as if fully set forth herein. This Count is brought by Relator Theis in the name of the United States under the *qui tam* provisions of 31 U.S.C. §3730 for defendants' violations of 31 U.S.C. §3729.

129. By virtue of the above-described acts, among others, defendants knowingly presented, and continue to present, directly or indirectly to officers, employees or agents of the United States, false or fraudulent claims for payment or approval.

130. By virtue of the above-described acts, among others, defendants knowingly made, used, or caused to be made or used, and may continue to make, use, or cause to be made or used, false records and statements to obtain payment from the United States for false or fraudulent claims.

131. By virtue of the above-described acts, defendant knowingly made or used false statements to avoid or conceal obligations to the United States.

132. The false or fraudulent claims to the United States were material.

133. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by defendants, and in reliance on the accuracy thereof, paid and may continue to pay false or fraudulent claims submitted by the defendants.

134. The United States sustained damages because of the defendants' actions.

#### **JURY DEMAND**

135. Plaintiffs demand trial by jury on all claims.

#### **PRAYER**

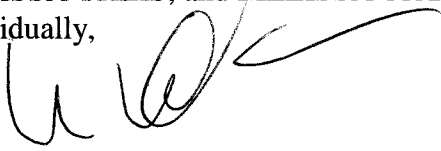
136. WHEREFORE, plaintiffs pray for judgment against defendant as follows:

- a. That defendants be found to have violated and be enjoined from future violations of the federal False Claims Act, 31 U.S.C. §3729-32.
- b. That this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States Government has sustained because of defendants' false or fraudulent claims, plus the maximum civil penalty for each violation of 31 U.S.C. §3729.
- c. That plaintiffs be awarded the maximum amount allowed pursuant to § 3730(d), and all relief to which they are entitled pursuant to §3730(h) of the False Claims Act.
- d. That plaintiffs be awarded all costs of this action, including expert

witness fees, attorneys' fees, and court costs.

- e. That plaintiffs recover such other relief as the Court deems just and proper.

Respectfully submitted,  
UNITED STATES OF AMERICA *ex rel.*  
MELISSA THEIS, and MELISSA THEIS,  
individually,

By:   
Linda Wyetzner

Date: March 30, 2009  
Linda Wyetzner  
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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel.*  
MELISSA THEIS, and MELISSA  
THEIS, individually,

Plaintiffs,

v.

NORTHWESTERN UNIVERSITY,  
THE ROBERT H. LURIE COMPREHENSIVE  
CANCER CENTER OF NORTHWESTERN  
UNIVERSITY, DR. STEVEN T. ROSEN, AND  
DR. CHARLES L. BENNETT.

Defendants.

09CV1943  
JUDGE HOLDERMAN  
MAG. SCHENKIER

CHIEF JUDGE HOLDERMAN  
FILED UNDER SEAL

**FILED**  
MAR 30 2009

THOMAS G BRUTON  
CLERK U S DISTRICT COURT

**NOTICE OF FILING AND CERTIFICATE OF SERVICE**

**PLEASE TAKE NOTICE** that on March, 30, 2009 the undersigned attorney filed with the Clerk of Court the enclosed *False Claims Act Complaint and Jury Demand*.

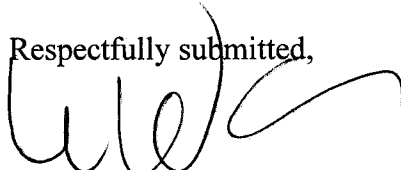
The undersigned attorney also hereby certifies that he caused a copy of the foregoing to be served upon the following persons as indicated.

Attorney General Eric H. Holder, Jr.  
c/o Director Joyce Branda  
United States Department of Justice  
950 Pennsylvania Ave., N.W.  
Washington, DC 20530  
*Via Certified Mail - RRR*

Hon. Patrick J. Fitzgerald  
c/o AUSA Linda Wawzenski  
Deputy Chief, Civil Division  
219 South Dearborn, Suite 500  
Chicago, IL 60604  
*Via Messenger*

Respectfully submitted,

By:

  
Linda Wyetzner

Date: March 30, 2009  
Linda Wyetzner and Asher Funk  
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